

April 25, 2001

Kimberly Topper
FDA
5630 Fishers Lane
Room 1091
Rockville, MD 20852

RE: OTC Hearing

Dear Ms. Topper,

For the past three years I have served as both Chairman of the Practice, Diagnostics, and Therapeutics Committee and Chairman of the Practice Standards Council of the American Academy of Allergy, Asthma and Immunology. In addition, for the past 20 years of my association at Harvard Medical School I have had the honor of training a number of physicians interested in the field of allergy and immunology in my role as Co-Director of the Allergy Fellowship Training Program, for which I have been an administrator for nearly ten years.

I am very troubled and disturbed by recent developments at the FDA related to consideration of a change in the classification for medications for allergic rhinitis and asthma from prescription status to over-the-counter status.

Although there is no significant mortality associated with allergic rhinitis, there is significant disease co-morbidity. Many patients with allergic rhinitis suffer from concomitant asthma, allergic conjunctivitis, chronic serous otitis and chronic sinusitis. The availability of non-sedating antihistamines or intranasal corticosteroids as over-the-counter medications would lure patients with significant allergic rhinitis away from the office of practicing physicians who are capable of diagnosing these co-morbid conditions often associated with allergic rhinitis.

The failure to diagnose concomitant asthma or chronic sinusitis could lead to significant harm occurring to patients. Allowing the progression of allergic disease that otherwise would be diagnosed through appropriate intervention occurring in a physician's office could cause significant morbidity to occur consequent to under-diagnosed and under-treated asthma and sinus disease.

Close to 40 million Americans have allergic rhinitis and associated conditions. Over 5 million Americans have allergic asthma. The overall economic impact of asthma and allergic rhinitis exceeds 10 billion dollars annually. This figure includes the cost of in-patient exacerbations of asthma and time lost from work and school in addition to losses in worker productivity. Up to 80% of asthmatics have had some allergic component, and up to 60% of patients with allergic rhinitis may at some point manifest symptoms of asthma. Those patients having both allergic rhinitis and asthma have approximately twice the overall cost of patients having asthma without allergic rhinitis. Allergic rhinitis is a significant risk factor for exacerbation of asthma. Failure to appropriately treat allergic rhinitis can lead to significant worsening of underlying asthma, placing patients at considerable long-term risk.

It is highly unreasonable and medically undesirable for patients to be provided greater incentives to self medicate for allergic disease such as allergic rhinitis and asthma. It cannot be expected that patients would understand or recognize the development of co-morbid conditions such as chronic sinusitis associated with allergic rhinitis or subtle signs and symptoms of asthma which may complicate allergic rhinitis. Failure to appreciate the occurrence of such co- morbid conditions will place patients at considerable risk. The restriction of the intranasal corticosteroids and non-sedating antihistamines to prescription-only status affords a chance for physicians to intervene in the care of such patients, thereby providing some level of protection against under-diagnosis and failure to appreciate disease progression.

Removing prescription non-sedating antihistamines and prescription intranasal corticosteroids from prescription status to over-the-counter status places patients with allergic rhinitis at significant risk simply because it removes from the diagnostic and therapeutic decision the intervention of well-trained health care providers, including physicians trained in the field of allergy.

It is in this regard that the allergy community, including myself, hope that the FDA will continue to require prescription coverage for non-sedating antihistamines and intranasal corticosteroid in addition to inhaled bronchodilators required for asthma management. The erroneous assumption that patients can self-medicate for allergic rhinitis and asthma, while economically

enticing, as it could potentially increase the access of medications to patients who would no longer require an office visit to a health care provider, ultimately will prove to be not in the best interest of the health care of the patients involved. The adverse consequences that can occur with inappropriate utilization of medications by patients who are not fully aware of the consequences of the diseases which they treat will ultimately have significant long-term adverse consequences related to the standard of health care provided to patients with allergic disease. It is unreasonable to expect that the public will be able to manage their allergic disease more appropriately than physicians trained in such disease management. The adverse consequences which will occur to the public related to failure to seek early intervention by a physician for the appropriate diagnosis and treatment of allergic rhinitis and asthma will ultimately have a significant adverse impact on public health.

As an educator of physicians in asthma and allergy disease management, I urge the FDA to maintain prescription coverage for non-sedating antihistamines, intranasal corticosteroids, inhaled bronchodilators, and inhaled anti-inflammatory medications for asthma, all of which require sophisticated training of a medical professional for their appropriate administration. The movement of any of these medications to over-the-counter status could place patients with allergic disease at significant risk and ultimately increase morbidity and mortality of allergic asthma.

The overall impact on asthma and allergic disease health care of movement of the treatment of these diseases to over-the-counter status definitely outweighs the potential benefit of allowing greater access to patients to these medications. Movement of these medications to over-the-counter status will not improve care of allergy and asthma patients but will only further compromise their care through inappropriate utilization of these therapies.

Sincerely,
Lawrence M. DuBuske, M.D.

LMD/bw